

REMARKS

1. In response to the Office Action mailed May 6, 2010, Applicants respectfully request reconsideration. Claims 54-82 were last presented for examination. Of these claims 66-69 and 82 are withdrawn. In the outstanding Office Action, claims 54-65 and 70-81 were rejected. By the foregoing Amendments, claims 54, 70-75 and 77-81 have been amended, claims 55, 76 and 82 have been cancelled, and new claims 83 and 85 have been added. Upon entry of this paper, claims 54, 56-75, 77-81 and 83-85 will be pending in this application. Of these twenty-nine (29) claims, three (3) claims (claims 54, 70 and 84) are independent.
2. Based upon the above Amendments and following Remarks, Applicants respectfully request that all outstanding objections and rejections be reconsidered, and that they be withdrawn.

Claim Objections

3. Claims 66-69 and 82 objected to as having incorrect status indicators. Applicants have changed the status indicators, as seen above, and respectfully request reconsideration.
4. Claims 54 and 70 are objected to as allegedly containing informalities. In response, Applicants have amended claims 54 and 70, as seen above, in accordance with Examiner Kahelin's recommendations, and request reconsideration. Applicants thank Examiner Kahelin for taking the time to recommend changes to overcome the rejections.

Claim Rejections – 35 USC § 103

5. Claims 54-65 and 70-81 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kramm et al. (U.S. Patent No. 6,936,040, hereinafter "Kramm") in view of Kuzma (U.S. Patent No. 6,309,410, hereinafter "Kuzma"). In response, Applicants have incorporated the recitations of previously pending claim 55 into independent claim 54, effectively placing previously pending claim 55 into independent form, and traverse the rejection of previously pending claim 55 (now claim 54). Applicants further amend claim 70, as seen above, in order to advance prosecution. Applicants respectfully submit that the claims are allowable in view of the cited references.

6. Claim 54 (previously pending claim 55), recites in part a cochlear implant comprising “an electrode assembly comprising a lead extending from the stimulator unit . . . an annular collar slideably mounted around the lead . . . and a stop member, disposed on the electrode assembly, configured to prevent the collar from sliding beyond the stop member toward a distal end of the elongate member.” (See, Claim 54, emphasis added.)

7. In rejecting previously pending claim 55 (now claim 54), the Office Action asserts that “it would have been obvious . . . to provide Kramm’s invention with a stop on the lead that prevents the positioning device from moving past the stop means to provide the predictable result of avoiding damage to tissue from too deep of insertion and ensuring proper placement of the electrodes.” (Office Action, page 6, lines 10-14.) Applicants respectfully disagree.

8. Modifying Kramm as proposed would render Kramm unusable for its intended purpose, and thus the proposed modifications are not obvious. Applicants rely on MPEP § 2143.01,V, entitled, *The Proposed Modification Cannot Render The Prior Art Unsatisfactory For Its Intended Purpose*, which states that if a “proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification. *In re Gordondon*, 733 F.2d 900, 221 USPQ 1125 (Fed. Cir. 1984).”

9. The device of Kramm is a “guide catheter” 40/40a, which is used to guide an electrical lead to the heart of a patient. That is, the guide catheter 40/40a is first snaked to the heart, and then an electrical lead with the alleged elongate member at the distal end of the lead is moved through the catheter 40/40a (and thus through the alleged collar 48) and out the catheter 40/4a to the heart. (See, Kramm, col. 5, lines 37-39.) If Kramm were modified to include a stop as recited in claim 54, the distal end of the electrical lead of Kramm would not be able to move through the catheter of Kramm to exit the catheter. This is because a stop “configured to prevent the collar from sliding beyond the stop member toward a distal end of the elongate member” would necessarily prevent the distal end of the electrical leads from being pushed past the alleged collar 48, and thus into the heart. This is because any other placement of the stop member would permit the alleged collar from sliding beyond the stop member towards a distal end of the electrical lead.

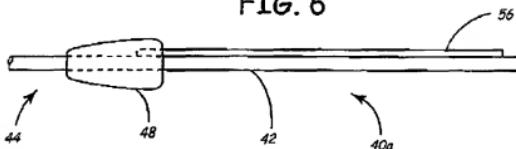
10. Accordingly, if Kramm is modified as proposed in the Office Action to include the recited stop member of claim 54, Kramm could not function for its intended purpose. Accordingly, a *prima facie* case of obviousness has not been established with respect to

previously pending claim 55 (now claim 54), and claim 54 and its dependencies are allowable for at least this reason.

11. Claim 63, which depends from claims 62 and 54, recites that the collar further comprises an inlet in fluid communication with the chamber, "wherein the inlet is disposed in a proximal end of the collar, and the outlet is disposed in a distal end of the collar."

12. The Office Action does not adequately address the recitation of the locations of the inlet and the outlet. The Office Action points to "an arbitrary point on 56 proximal to 48 such that the outlet is on the 'distal end' of the collar structure." (Office Action, page 5, last paragraph.) As may be seen from FIG. 6 of Kramm, reproduced below, element 56 does not extend through element 48, thus, no "arbitrary point on 56" corresponds to "an outlet disposed on the distal end of the collar," in accordance with claim 63.

FIG. 6



13. Further, the recitation of claim 65 of "a pipe extending through the collar from the inlet to the outlet" is not taught in Kramm, contrary to the assertions of the Office Action in the last paragraph of page 5. Again referring to FIG. 6 of Kramm, it is clear that any alleged pipe fails to extend from an inlet to an outlet of the alleged collar. This is yet another claim not rendered obvious by Kramm.

14. Amended independent claim 70 recites an implantable tissue stimulating device comprising "an electrode assembly comprising a lead and an elongate member," and a slider means for delivery of a bioactive substance slidably mounted on the lead such the lead extends through the slider means." (See, Claim 70, emphasis added.)

15. Claim 70 has been written as a "means-plus-function" claim pursuant to 35 U.S.C. §112, sixth paragraph. Accordingly, to reject claim 70 in the future, the PTO must show that any alleged "slider means for delivery of a bioactive substance" is the same as or equivalent to the structure, material or acts described in Applicants' specification. Specifically, MPEP § 2182, entitled "Scope of the Search and Identification of the Prior Art," states that

if a prior art reference teaches identity of function to that specified in a claim, then under *Donaldson* an examiner carries the initial burden of proof for showing that the prior art structure or step is the same as or equivalent to the structure, material, or acts described in the specification which has been identified as corresponding to the claimed means or step plus function.

(MPEP § 2182, citing *In re Donaldson* (16 F.3d 1189 (Fed. Cir. 1994)).)

16. The “slider means for deliver of a bioactive substance” corresponds to the collar 240 of Fig. 19 of Applicants’ specification. The “distribution device” 48 of Kramm alleged to correspond to the previously recited collar is not the same as the structure depicted in Fig. 19 and respectively described in Applicants’ specification. The “distribution device” 48 of Kramm is also not an equivalent to that structure. Accordingly, claim 70 and its dependencies are allowable for at least this reason.

17. Claims 80 and 81 are allowable for the pertinent reasons detailed above with respect to claims 63 and 64.

18. Allowance of the application is requested.

Dependent Claims

19. The dependent claims incorporate all the subject matter of their respective independent claims and add additional subject matter which makes them independently patentable over the art of record. Accordingly, Applicants respectfully assert that the dependent claims are also allowable over the art of record.

New Claims

20. New claims 83-85 have been added. New claim 83 is allowable due to its dependency from claim 70, a claim that is allowable as detailed above.

21. New claim 84 recites a cochlear implant comprising “an annular collar slidably mounted around the lead such that the lead extends through a lumen in the collar, the collar having a non-porous cavity therein configured to receive a bioactive substance and an outlet located on an exterior face of the collar through which the bioactive substance can pass from the cavity to a target site in the recipient, wherein the outlet faces the electrode assembly and forms a boundary of the cavity.” (See, Claim 84, emphasis added.) Any non-porous cavity of Kramm with an outlet that forms a boundary of said cavity does not have an outlet located on an exterior face of the collar that faces an electrode assembly as recited. Claim 84 is allowable for at least this reason.

22. New claim 85 recites that the “outlet comprises a valve configured to allow the bioactive substance contained in the cavity to exit the cavity and at least substantially prevent fluid flow from external the cavity into the cavity.” (See, Claim 85.) Kramm fails to teach such a feature. Claim 85 is thus allowable for at least this reason.

Conclusion

23. In view of the foregoing, this application should be in condition for allowance. A notice to this effect is respectfully requested.

24. Applicant reserves the right to pursue any cancelled claims or other subject matter disclosed in this application in a continuation or divisional application. Any cancellations and amendments of above claims, therefore, are not to be construed as an admission regarding the patentability of any claims and reserves the right to pursue such claims in a continuation or divisional application.

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